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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,862	05/27/2005	Jan-Christoph Wollmann	175.8163USU	4598
27623 7590 06/23/2009 OHLANDT, GREELEY, RUGGIERO & PERLE, LLP ONE LANDMARK SQUARE, 10TH FLOOR STAMFORD, CT 06901				
EXAMINER KOHARSKI, CHRISTOPHER				
ART UNIT		PAPER NUMBER		
3763				
MAIL DATE		DELIVERY MODE		
06/23/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/536,862

Applicant(s)

WOLLMANN ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 2/17/2009 in which claims 1-10 were amended and new claims 11-16 were added. Currently claims 1-16 are pending for examination in this application. Additionally, the Examiner also acknowledges the amendments to the specification filed 2/17/2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tischlinger (USPN4,059,109). Tischlinger et al. discloses a mixing and dispensing disposable medicament injector.

Regarding claims 1-16, Tischlinger et al. discloses a device capable of producing medicinal foam (Figures 1-2), comprising: an active agent chamber (A) closed with a first piston (66), a gas chamber (B) closed with a second piston (90), a hollow needle (94) connected to the second piston (90), the hollow needle 994) having an open end directed towards the first piston (66), an entrainment element (bearing around needle 94, between the needle and piston) rigidly connected to the hollow needle (94) offset from the open end, openings defined through the second piston (near 94) and/or through transverse bores of the hollow needle (94), and a foam producing device

(needle 164) connected with the hollow needle (94, via fluid flow) and the openings, wherein the hollow needle (94) is capable of interconnecting the first and second pistons in common to feed active agent through the hollow needle and gas through the openings to the foam producing device upon displacement of the hollow needle (94) through the first piston (66) to a point where the entrainment element contacts the first piston 966), wherein the foam producing device (needle 164) is removably connected to the second piston by a holder (Figures 1-2), wherein the holder comprises a foam exit opening (distal end of tube 12) wherein the foam exit opening comprises a Luer to which a conventional syringe is connectable (end near 112), and wherein the active agent chamber and the gas chamber are arranged one after the other (longitudinally, Figures 1-4).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Drake (USPN 4,538,920).

Regarding claims 1, 6, and 8, Drake discloses a device with two chambers (Fig 1) each with piston (4) that when displaced, opens one of the chambers. Both chambers coupled to the pistons are coupled with a foam producing means (7). The foam

producing means (7) configured to pass the components through each other, functioning as a sieve.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US2002/0101785) in view of Brony (USPN 5,454,805)

Regarding claims 1 and 8, Edwards et al. discloses two chambers (12,14) and two pistons (44) which are connected and when displaced opens at least one chamber. Both chambers are connected and fluid may flow through. However, Edwards et al. does not disclose a foam producing member. Brony discloses the use of a sieve (Col. 3, Lines 16-17) which allows fluid to flow through multiple holes which would then mix. Though Brony does disclose the use of two liquids, a gas component could also be combined through the sieve. The forcing of liquid and gas through a sieve would create

a foam. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the connector of Edwards et al. with the connector of Brony to include a sieve for mixing two components.

Regarding claims 6-7, Edwards et al. in view of Bony substantially discloses all of the claimed limitations as set forth above. The pistons of Edwards et al. are coupled to the housing of syringes. Bony discloses the coupling of the sieve to the housing of the needless syringe. Additionally the connector (62) of Edwards et al. would allow the foam to flow to one of the syringes which could store and then dispense the foam. It would have been obvious to one of ordinary skill in the art at the time of the invention that the connector of Edwards et al. modified by the sieve of Brony would allow the foam to flow to one of the syringes for storage and dispensing.

Claims 2, 5, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('785).

Edwards et al. in view of Brony substantially discloses all of the claimed limitations as set forth above. Further, Edwards et al. discloses a feed channel (62) which connects the two adjoining chambers (Fig. 5). Additionally Edwards et al. discloses a syringe which narrows before passing through the connecting element, slowing down the flow of the material. Finally when not attached to the second syringe, one syringe of Edwards et al. has an opening (54) from which material can flow. It would have been obvious to one of ordinary skill in the art at the time of the invention that the two chambers are connected and that the narrowing of the syringe to the exit port would slow the flow of the material.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. ('785) in view of Lockhart (USPN 2,724,383).

Regarding claims 3-4, Edwards et al. substantially discloses all of the claimed limitations as set forth above. However Edwards et al. does not disclose a segregation of the two chambers once connected. Lockhart teaches a connecting element (34) coupled to an entrainment element (31). This connecting element is responsible for opening the chambers which are then connected through the connecting element. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the connector of Edwards et al. with the connecting element of Lockhart to better control the combining of the elements within the two chambers.

Response to Arguments

Applicant's arguments filed 02/17/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Drake (USPN 4,538,920) does not disclose two pistons interconnected and that combination of Edwards et al. (US2002/0101785) in view of Brony (USPN 5,454,805) is not proper.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

The Examiner asserts that Drake (USPN 4,538,920) reference meets the claim limitations as claimed. The Drake reference discloses two piston elements that are connected via a jointed handle assembly (6), Figure 2 best shows the two piston rod elements that are joined by the proximal most handle portion (near 6). Further Drake

discloses the two piston chambers arranged one after another in the horizontal direction (Figure 2). Regarding the combination of Edwards et al. (US2002/0101785) in view of Brony (USPN 5,454,805), the Examiner asserts that both devices are in the same field of endeavor. Both devices are used to hold and deliver medical compositions to patients.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the entrainment element, needle, and first/second piston arrangement (as shown in Figures 1-3).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 6/21/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

